

tests: Does not exceed \$10,000 in value as determined through reference to public prices or other reasonable measures of fair market value, and does not represent more than a five percent ownership interest in any single entity; or

(6) Salary, royalties or other payments that when aggregated for the investigator and the investigator's spouse and dependent children over the next twelve months, are not reasonably expected to exceed \$10,000.

Small Business Innovation Research (SBIR) Program means the extramural research program for small business that is established by the awarding components of the Public Health Service and certain other Federal agencies under Public Law 97-219, the Small Business Innovation Development Act, as amended. For purposes of this part, the term SBIR Program includes the Small Business Technology Transfer (STTR) Program, which was established by Public Law 102-564.

§ 94.4 Institutional responsibility regarding conflicting interests of investigators.

Each Institution must:

(a) Maintain an appropriate written, enforced policy on conflict of interest that complies with this part and inform each Investigator of that policy, the Investigator's reporting responsibilities, and of these regulations. If the Institution carries out the PHS-funded research through subcontractors, or collaborators, the Institution must take reasonable steps to ensure that Investigators working for such entities comply with this part, either by requiring those Investigators to comply with the Institution's policy or by requiring the entities to provide assurances to the Institution that will enable the Institution to comply with this part.

(b) Designate an institutional official(s) to solicit and review financial disclosure statements from each Investigator who is planning to participate in PHS-funded research.

(c)(1) Require that by the time an application is submitted to PHS, each Investigator who is planning to participate in the PHS-funded research has submitted to the designated official(s)

a listing of his/her known Significant Financial Interests (and those of his/her spouse and dependent children):

(i) that would reasonably appear to be affected by the research for which PHS funding is sought; and

(ii) in entities whose financial interests would reasonably appear to be affected by the research.

(2) All financial disclosures must be updated during the period of the award, either on an annual basis or as new reportable Significant Financial Interests are obtained.

(d) Provide guidelines consistent with this part for the designated official(s) to identify conflicting interests and take such actions as necessary to ensure that such conflicting interests will be managed, reduced, or eliminated.

(e) Maintain records of all financial disclosures and all actions taken by the Institution with respect to each conflicting interest for three years after final payment or, where applicable, for the other time periods specified in 48 CFR part 4, subpart 4.7.

(f) Establish adequate enforcement mechanisms and provide for sanctions where appropriate.

(g) Certify, in each contract proposal, that:

(1) there is in effect at that Institution a written and enforced administrative process to identify and manage, reduce or eliminate conflicting interests with respect to all research projects for which funding is sought from the PHS;

(2) prior to the Institution's expenditure of any funds under the award, the Institution will report to the PHS Awarding Component the existence of any conflicting interest (but not the nature of the interest or other details) found by the Institution and assure that the interest has been managed, reduced or eliminated in accordance with this part; and, for any interest that the Institution identifies as conflicting subsequent to the Institution's initial report under the award, the report will be made and the conflicting interest managed, reduced, or eliminated, at least on an interim basis, within sixty days of that identification.

(3) the Institution agrees to make information available, upon request, to

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the HHS regarding all conflicting interests identified by the Institution and how those interests have been managed, reduced, or eliminated to protect the research from bias; and

(4) the Institution will otherwise comply with this part.

[60 FR 35817, July 11, 1995; 60 FR 39076, July 31, 1995]

§ 94.5 Management of conflicting interests.

(a) The designated official(s) must: Review all financial disclosures; and determine whether a conflict of interest exists, and is so, what actions should be taken by the institution to manage, reduce, or eliminate such conflict of interest. A conflict of interest exists when the designated official(s) reasonably determines that a Significant Financial Interest could directly and significantly affect the design, conduct, or reporting of the PHS-funded research. Examples of conditions or restrictions that might be imposed to manage conflicts of interest include, but are not limited to:

(1) Public disclosure of significant financial interests;

(2) Monitoring of the research by independent reviewers;

(3) Modification of the research plan;

(4) Disqualification from participation in all or a portion of the research funded by the PHS;

(5) Divestiture of significant financial interests, or;

(6) Severance of relationships that create actual or potential conflicts.

(b) In addition to the types of conflicting financial interests described in this paragraph that must be managed, reduced, or eliminated, an Institution may require the management of other conflicting financial interests, as the Institution deems appropriate.

[60 FR 35817, July 11, 1995; 60 FR 39077, July 31, 1995]

§ 94.6 Remedies.

(a) If the failure of an Investigator to comply with the conflict of interest policy of the Institution has biased the design, conduct, or reporting of the PHS-funded research, the Institution must promptly notify the PHS Awarding Component of the corrective action

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taken or to be taken. The PHS Awarding Component will consider the situation and, as necessary, take appropriate action or refer the matter to the institution for further action, which may include directions to the Institution on how to maintain appropriate objectivity in the funded project.

(b) The HHS may at any time inquire into the Institutional procedures and actions regarding conflicting financial interests in PHS-funded research, including a review of all records pertinent to compliance with this part. HHS may require submission of the records or review them on site. To the extent permitted by law HHS will maintain the confidentiality of all records of financial interests. On the basis of its review of records and/or other information that may be available, the PHS Awarding Component may decide that a particular conflict of interest will bias the objectivity of the PHS-funded research to such an extent that further corrective action is needed or that the Institution has not managed, reduced, or eliminated the conflict of interest in accordance with this part. The issuance of a Stop Work Order by the Contracting Officer may be necessary until the matter is resolved.

(c) In any case in which the HHS determines that a PHS-funded project of clinical research whose purpose is to evaluate the safety or effectiveness of a drug, medical device, or treatment has been designed, conducted, or reported by an Investigator with a conflicting interest that was not disclosed or managed as required by this part, the Institution must require disclosure of the conflicting interest in each public presentation of the results of the research.

[60 FR 35817, July 11, 1995; 60 FR 39077, July 31, 1995]

PART 95—GENERAL ADMINISTRATION—GRANT PROGRAMS (PUBLIC ASSISTANCE AND MEDICAL ASSISTANCE)

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